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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,222	11/20/2003	Fred H. Burbank	R0368-03100	9030

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,222	BURBANK ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14, 16-20 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-32 is/are allowed.
- 6) ☒ Claim(s) 1,3,9-12, 14, 16-20, 22-24, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 4-8 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
:6/14/06,8/5/05,1/31/05,10/4/04,5/26/04,4/22/04.

DETAILED ACTION

Response to Arguments

Regarding 112 Rejections

Applicant's arguments with respect to claim 3 have been considered but are not persuasive. As described in the previous office action, Claim 3 recites the limitation "the extendable wall" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites a wall "configured to extend distally", which does not claim the explicitly state that the wall is extendable, it simply states that the wall is present and it extends or is positioned in the distal direction. Claims 4-8 and 13 are also rejected as being dependent off of rejected claim 3

Applicant's arguments with respect to claim 3 have been considered but are not persuasive. As described in the previous office action, Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim language of claim 23 is unclear in line 6. With respect to the phrase "which has at least one distally extending curtain," it is unclear as to what the term "which" is referring, i.e. the closed proximal end or the cervical receptacle.

Applicant's arguments, see page 10, filed 12/19/06, with respect to claim 33 have been fully considered and are persuasive. The 35 USC 112 rejection of claim 33 has been withdrawn.

Regarding the combination of Burbank and Nagel Reference

Applicant's arguments, see page 10, filed 12/19/06, with respect to Nagel have been fully considered but are not persuasive. Applicant argues that the addition of the limitation requiring at least one groove in the wall of the cervical receptacle, which is in fluid communication with the lumen in the shaft distinguishes these claims over the cited reference. Examiner respectfully disagrees. As described in the previous office action, Nagel teaches wherein a cervical groove (26) is both present and in fluid communication with the lumen in the shaft. Thus, examiner sustains the previous rejection with respect to the combination of Burbank and Nagel.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-8 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the extendable wall" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites a wall "configured to extend distally", which does not explicitly state that the wall is extendable, it simply states that the wall is present and it extends or is positioned in the distal direction. Claims 4-8 and 13 are also rejected as being dependent off of rejected claim 3

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Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim language of claim 23 is unclear in line 6. With respect to the phrase "which has at least one pressure applying surface," it is unclear as to what the term "which" is referring, i.e. the closed proximal end or the cervical receptacle, claim 24 is further rejected as being dependent off of claim 23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 9-12, 14, 16-22, 33, 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. (US 2002/0165579) in view of Nagel (US 2400251).

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Burbank teaches an intravaginal uterine artery occlusion device comprising the following:

- an elongated shaft (202) which has a distal end,
- a cervical receptacle (204) which is secured to the distal end of the elongated shaft, which has an open distal end and an interior configured to receive at least part of a female patient's uterine cervix
- A wall portion (402) at the distal end of the cervical receptacle which is configured to extend distally from the open distal end of the receptacle and which has at least one distal pressure applying surface (414) to facilitate occlusion of the patient's uterine artery.
- Wherein cervical receptacle is configured to be disposed about the patients uterine cervix when the extendable wall (it is noted that paragraph 51 denotes constant force generating member 410 as a helical spring, which is inherently extendable) is distally extended so that the pressure applying surface thereon applies pressure to the patients vaginal fornix.
- wherein the distal pressure applying surface has a blood flow sensor (302i) to facilitate location of the patient's uterine artery
- wherein the blood flow sensor is a Doppler ultrasound sensor
- wherein the Doppler ultrasound sensor is configured to sense ultrasound energy having a frequency of about 8 MHz (par. 48).

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- wherein at least one blood flow sensor has a sensing direction distally away from the pressure applying surface of the wall portion to facilitate detection of the patient's uterine artery (fig. 7a).
- wherein the interior of the receptacle is configured to receive the patient's cervix and part of the patient's vaginal fornix so that the leading edge of the receptacle applies sufficient pressure to the vaginal fornix to occlude the patient's uterine artery (par. 17).
- The device of claim 1 wherein the pressure applying surface is part of an occlusion bar (206, 208).
- Wherein the device comprises a plurality of sensors (fig. 7a).
- wherein the uterine artery remains occluded by pressure applied by the leading edge of the cervical receptacle for a limited time ranging from about 0.2 to about 24 hours and more specifically, from about 0.5 to about 16 hours (par. 72 as incorporated by U.S. application #09/556,934)

Burbank fails to disclose:

- Wherein the elongated shaft has an inner lumen configured to be interconnected to a vacuum source and extending to the distal end;
- wherein the cervical receptacle has an elongated cervical sound within the interior thereof configured to be guided into a female patient's cervical canal to thereby position the receptacle about the exterior of the patient's cervix
- wherein the elongated cervical sound is provided with a rounded non-traumatic distal tip

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- wherein the cervical receptacle has at least one groove in an inner surface which is in fluid communication with the lumen in the shaft
- wherein the at least one groove is parallel to a central axis of the receptacle
- wherein the cervical receptacle has a lowered anterior lip, which facilitates deploying the receptacle about the patient's uterine cervix

Regarding the limitations requiring a vacuum, Nagel teaches a gynecological device wherein the elongated shaft has an inner lumen configured to be interconnected to a vacuum source and extending to the distal end; and the interior of the cervical receptacle is configured to be in fluid communication with the inner lumen in the shaft (see fig. 1 and claim 2) in order to draw the cervix into the cavity (fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Burbank with an inner lumen to be connected to a vacuum source as taught by Nagel in order to facilitate drawing the cervix into the cavity of the device.

Regarding the limitation requiring a cervical sound, Nagel teaches a device wherein the cervical receptacle has an elongated cervical sound with a rounded tip (36) within the interior thereof, in order to give fixation to the uterus and manipulate the device with out damaging tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Burbank with an elongated cervical sound as taught by Nagel in order to give fixation to the uterus and manipulate the device without damaging tissue.

Regarding the limitations requiring wherein the cervical receptacle has at least one groove parallel to a central axis of the receptacle in an inner surface, in fluid

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communication with the lumen in the shaft and wherein the cervical receptacle has a lowered anterior lip, Nagel teaches a device wherein the cervical receptacle has at least one groove in an inner surface in fluid communication with the lumen in the shaft (Column 1, proximate lines 50-55 to Column 2, proximate lines 1-3, fig. 3), wherein the at least one groove is parallel to a central axis of the receptacle (Column 1, proximate lines 50-55 to Column 2, proximate lines 1-3), and wherein the cervical receptacle has a lowered anterior lip, in order to provide fixation and relatively easy manipulation of body parts to position the instrument. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Burbank with at least one groove parallel to a central axis of the receptacle in an inner surface and wherein the cervical receptacle has a lowered anterior lip in order to provide fixation and relatively easy manipulation of body parts to position the instrument.

Allowable Subject Matter

Claims 4-8, 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 25-32 are allowed. The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to teach a method of treating a female patients uterine disorder which includes occluding a female patients uterine artery comprising a cervical receptacle having an open distal end, a closed proximal

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end, and at least one pressure applying surface which is part of at least one distally extendable curtain.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
2/26/07


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
